510(k) SUMMARY

FEB 1 2 2013

SUBMITTER:	Sorin Group Italia 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	January 25, 2013
DEVICE TRADE NAME:	INSPIRE 6 hollow fiber oxygenator with integrated hardshell venous/cardiotomy reservoir INSPIRE 6F hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir
COMMON NAMES:	INSPIRE 6: Hollow Fiber Oxygenator with integrated hardshell venous/cardiotomy reservoir Hollow Fiber Oxygenator Hardshell Venous/Cardiotomy Reservoir INSPIRE 6F: Hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir Hollow Fiber Oxygenator with integrated arterial filter Hardshell Venous/Cardiotomy Reservoir
CLASSIFICATION NAME:	INSPIRE 6: Cardiopulmonary Bypass Oxygenator/ Cardiopulmonary Bypass Heat Exchanger/ Cardiopulmonary Bypass Blood Reservoir/ Cardiopulmonary Bypass Defoamer INSPIRE 6F: Cardiopulmonary Bypass Oxygenator/ Cardiopulmonary Bypass Heat Exchanger/ Cardiopulmonary Bypass Blood Reservoir/ Cardiopulmonary Bypass Defoamer/ Cardiopulmonary Bypass Arterial Line Blood Filter
UNMODIFIED DEVICES:	INSPIRE 6 hollow fiber oxygenator with integrated hardshell venous/cardiotomy reservoir (K113626) INSPIRE 6F hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir (K120185)

DEVICE DESCRIPTION:

The INSPIRE 6 and INSPIRE 6F are high efficiency microporous hollow fiber membrane oxygenators integrated with heat exchanger (INSPIRE 6M and INSPIRE 6F M, respectively) and connected to a hardshell venous/cardiotomy reservoir (INSPIRE HVR). A molded fitting joint connects the oxygenator to the reservoir. As compared to the INSPIRE 6, the INSPIRE 6F oxygenating module is also integrated with an arterial filter.

The devices can be operated at flow rates up to 6 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood or suction blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The integrated arterial filter provides additional protection against air and solid emboli and the integrated hardshell reservoir collects, defoams, filters venous and suction blood, and can be used post-operatively for chest drainage.

The modified devices, hereafter referred to as INSPIRE 6/6F with modified HVR (Hardshell Venous Reservoir), are a modified version of the currently marketed INSPIRE 6 and INSPIRE 6F integrated systems.

INDICATION FOR USE:

The intended uses for the two elements that constitute the oxygenator/reservoir integrated devices are:

INSPIRE 6M: Hollow Fiber Oxygenator
INSPIRE 6M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6M is intended to be used for 6 hours or less.

INSPIRE 6F M: Hollow Fiber Oxygenator
The INSPIRE 6F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 6F M is intended to be used for 6 hours or less.

INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir
INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage. INSPIRE HVR is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The INSPIRE 6/6F with modified HVR have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices.

As compared to the unmodified devices, the INSPIRE 6/6F with modified HVR will be provided with a different shape of the plastic frame that supports the filtering system and with a different venous filter.

The shape of the plastic frame that supports the venous filter has been changed from a cylindrical to a conical profile.

The venous filter has been modified from a one-part design, consisting of a continuous double polyester screen on the whole filtering system (105µm internal and 41µm external), to a two-part design consisting of a single polyester screen for the upper part (120µm) and a double polyester screen for the lower part (120µm internal and 41µm external).

The modified hardshell venous/cardiotomy reservoir will be also provided with a different o-ring at the interface between the top of the reservoir housing and the lid. The modified o-ring has a reduced hardness to assure a seal.

No modification described in the present 510(k) applies to the oxygenating module, heat exchanger or arterial filter.

No change to the intended use has been made as a result of the modifications.

The INSPIRE 6/6F with modified HVR and the unmodified devices share the same fundamental technological characteristics except for some modifications that do not affect the basic device function. These differences do not raise any new issues of safety and effectiveness.

The INSPIRE 6/6F with modified HVR are substantially equivalent to the unmodified devices on the basis of operating principles and basic function.

There are no differences in packaging type and material between unmodified and modified device.

The INSPIRE 6/6F with modified HVR are ethylene oxide sterilized and have a non-pyrogenic fluid path. The devices are for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were conducted in accordance with the requirements of ISO 10993-1, USP class VI requirements, and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

IN VITRO TEST RESULTS:

In vitro testing was conducted in accordance with the relevant requirements of "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000; ISO 15674, "Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags".
In vitro testing was conducted on the modified reservoir to demonstrate unmodified reservoir substantial equivalency and compliance to safety and effectiveness requirements.

The present application includes no changes that apply to the oxygenating module or the oxygenating module integrated with the arterial filter.

The following table lists the performance and physical/mechanical integrity tests conducted to demonstrate compliance to the product's performance specifications. The modified hardshell venous/cardiotomy reservoir successfully met all acceptance criteria for each test.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Physical/Mechanical	Blood pathway integrity
2	Functional/Performance	Air handling
3	Functional/Performance	Break-through time and volume
4	Functional/Performance	Dynamic priming volume / Hold-up
5	Functional/Performance	Filtration efficiency - venous section
6	Functional/Performance	Flow rate capacity
7	Functional/Performance	Pressure drop
8	Functional/Performance	Hemolysis
9	Functional/Performance	Blood compatibility

CONCLUSIONS:

The results of in vitro studies demonstrate that the modified reservoir performs in a manner substantially equivalent to the unmodified reservoir with respect to the relevant functional parameters. Test results of this study demonstrate the INSPIRE 6/6F with modified HVR are equivalent to unmodified devices with respect to device function.
Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 1 2 2013

Sorin Group Italia S.R.I.
c/o Sorin Group USA, Inc.
14401West 65th Way
Arvada, Colorado, 80004
Attn: Mr. Scott Light

Re: K130209
INSPIRE 6 and 6F Hollow Fiber Oxygenator with Integrated Hardshell Reservoir (INSPIRE HVR)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: January 25, 2013
Received: January 29, 2013

Dear Mr. Light:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130209

Device Name: INSPIRE 6 hollow fiber oxygenator with integrated hardshell venous/cardiotomy reservoir

Indication for Use:

INSPIRE 6M: Hollow Fiber Oxygenator
INSPIRE 6M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6M is intended to be used for 6 hours or less.

INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir
INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage. INSPIRE HVR is intended to be used for 6 hours or less.

Device Name: INSPIRE 6F hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir

Indication for Use:

INSPIRE 6F M: Hollow Fiber Oxygenator
The INSPIRE 6F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 6F M is intended to be used for 6 hours or less.

INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir
INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage. INSPIRE HVR is intended to be used for 6 hours or less.

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K130209